

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

Appl. No. : 10/643,313  
Filed : August 18, 2003

### REMARKS

Claims 1-24 are currently pending in this application. Claims 1, 6, 11, 13, 15, 17, 19 and 20 have been amended. Reconsideration of the application in view of the following comments is respectfully requested.

#### Response to the Examiner's Comments

##### Reissue Oath/Declaration

The Examiner objected to the reissue oath/declaration submitted in this case as defective due to a typographical error with respect to the issue date of U.S. Patent No. 6,277,395. A ✓corrected reissue oath/declaration is submitted with this amendment. Applicants respectfully submit that the corrected reissue oath/declaration fully addresses the Examiner's concerns.

##### The New Matter Rejection Under 35 U.S.C. 251

#### "Swallowing the combination immediately after the combining step"

The Examiner rejected Claims 15-20 under 35 U.S.C. 251 as being based upon new matter. The Examiner stated in the first office action that Claims 15-20 recite a limitation, "swallowing the combination immediately after the combining step," that does not have support in the original issued patent. As explained above, during the telephone interview the Examiner stated that his objection was to the term "immediately" in the claim limitation. In order to respond to the Examiner's objection, Applicants have deleted the term "immediately" from Claims 15, 17, and 19-20, and have instead specified that swallowing occurs "in conjunction with" the combining step. This language is intended to indicate that the material to be swallowed is combined with the prepared material by the end user or someone assisting the end user, not during the manufacturing process that produces the "prepared form."

Applicants respectfully submit that the limitation as amended, "swallowing the combination in conjunction with the combining step," is fully supported by the specification. (See U.S. Patent No. 6,277,395; Col. 4, lines 15-22, stating that in one embodiment, the swallowing-assistive drink is poured into the mouth and swallowed together with the medicine, as well as several other instances indicating that one takes an already-prepared swallowing-assistive drink, which is then combined with a medicine and swallowed shortly thereafter.) Applicants respectfully submit that this objection has been overcome.

**Appl. No.** : **10/643,313**  
**Filed** : **August 18, 2003**

“Solid material”

The Examiner also rejected Claims 19 and 20 in the first office action, stating that the term “solid material” in the limitation “a method for swallowing a solid material, comprising the steps of ... combining the swallowing-assistive material with the solid material; wherein the solid material is enwrapped within the swallowing assistive material” does not have support in the original issued patent. As stated above, the Examiner withdrew this objection during the telephone interview.

The Written Description Requirement Rejection Under 35 U.S.C. 112, first paragraph

“Swallowing the combination immediately after the combining step”

The Examiner rejected Claims 15-20 in the first office action for failing to comply with the written description requirement of 35 U.S.C. 112, first paragraph. Specifically, the Examiner stated that the limitation “swallowing the combination immediately after the combining step” is not supported in the specification. As explained above, during the telephone interview the Examiner stated that his objection was to the term “immediately” in the claim limitation. In order to respond to the Examiner’s objection to the term “immediately” Applicants have amended the claims to remove the term “immediately” from Claims 15, 17, and 19-20, and have instead specified that swallowing occurs “in conjunction with” the combining step.

Applicants respectfully submit that the limitation as amended, “swallowing the combination in conjunction with the combining step,” is fully supported by the specification and conveys to one of ordinary skill in the art that the inventor(s) had possession of the claimed invention at the time the application was filed. (See U.S. Patent No. 6,277,395; Col. 4, lines 15-22, stating that in one embodiment, the swallowing-assistive drink is poured into the mouth and swallowed together with the medicine.) Applicants respectfully submit that amended Claims 15-20 comply with the written description requirement.

“Solid material”

The Examiner also rejected Claims 19-20 in the first office action as not supported by the specification. More specifically, the Examiner stated that the limitation “a method for swallowing a solid material, comprising the steps of ... combining the swallowing-assistive

**Appl. No.** : **10/643,313**  
**Filed** : **August 18, 2003**

material with the solid material; wherein the solid material is enwrapped within the swallowing assistive material” in Claims 19-20 is not supported by the specification. As stated above, the Examiner withdrew this objection during the telephone interview.

The §103(a) Rejection of Claims 1-24 over Speck et al

The PTO rejected Claims 1-24 as obvious over Speck et al. (U.S. Patent No. 5,010,061). The previous Examiner stated in the first office action that Speck et al. discloses drinkable compositions comprising water and paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid as well as methods for taking a medication. As discussed above, the Examiner has agreed that the “prepared form” limitation in Claims 15, 17, 19-21 and 23 distinguishes the claims over Speck et al. Applicants agreed during the telephone interview to add a related or similar limitation to the remaining independent claims to overcome the obviousness rejection over Speck et al. Accordingly, Claims 1 and 6 have been amended to include the product-by-process limitation “packaged in a prepared form in the absence of a medication prior to enwrapping the medicine” and Claims 11 and 13 have been amended to include the limitation “in a prepared form.” With respect to the composition claims, Applicants submit that the current product-by-process limitation defines a real difference in the end product, i.e., in the combination that is prepared containing the medicine, prior to being swallowed. A medicine that is mixed into an aqueous medium and then packaged will tend to interact with that aqueous medium, because medicines, as herein intended, interact with aqueous media over time through dissolution, dispersion, or otherwise; if not, they would not fulfill their intended function by interacting with the aqueous medium of the body. Thus, a bitter medicine, for example, that was pre-mixed in a packaged form with a swallowing-assistive drink would likely taste bitter to the end user. This can be distinguished from a swallowing-assistive drink that is pre-packaged in the absence of that medication, where the medicine is then mixed into that prepared product by the end user. Applicants respectfully submit that pending claims 1-24 are patentable over Speck et al. as Speck does not disclose, teach, or suggest the claimed invention.

Conclusion

In view of the foregoing, Applicants respectfully submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If,

Appl. No. : 10/643,313  
Filed : August 18, 2003

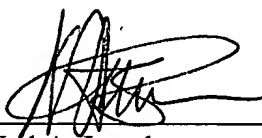
however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 6, 2004

By:   
Ned A. Israelsen  
Registration No. 29,655  
Attorney of Record  
Customer No. 20,995  
(619) 235-8550

H:\DOCS\CMP\CMP-1837.DOC  
070104

COPY

Page 1

Attorney's Docket No. RYUK.001R3

DECLARATION PURSUANT TO 37 C.F.R. 1.175 - USA REISSUE APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a reissue patent is sought on the invention entitled SWALLOWING-ASSISTIVE DRINK; the specification of which was filed on Mar. 11, 2000 as Application Serial No. 09/524,247, and issued on Aug. 21, 2001 as U.S. Patent No. 6,277,395.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

I believe that my original U.S. Patent No. 6,277,395 is wholly or partially inoperative or invalid by reason of the patentee claiming more or less than the patentee had a right to claim in the patent. Specifically, the claims, as originally issued, did not specifically claim a product that is in prepared form, uncombined with a medicine, or a method wherein the swallowing-assistive material is combined with a medicine and the combination is swallowed immediately after the combining step. This error is remedied in the present reissue application by the addition of Claims 15, 17, 19, and 20 to methods for taking a medicine and Claims 21 and 23 to swallowing assistive materials, which claims specifically include the desired limitations. In addition, the specification and claims replace the unconventional term "jelly strength" with the more idiomatic term "gel strength."

All errors which are being corrected in the present reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of the applicant;

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Atsuko Fukui

Inventor's signature Atsuko Fukui

Date 11 June 2004

Residence: 3-17-12 Misora Yotsukaido-city Chiba, Japan

Page 2

Attorney's Docket No. RYUK.001RE

Citizenship: Japan

Post Office Address: 2-4-8, Higashi Kanda, Chiyoda-ku, Tokyo, Japan

Full name of Second inventor: Masanori Nakajima

Inventor's signature Masanori Nakajima

Date 6.14.2004

Residence: 4-8-406, 4-chome, Masago, Mihama-ku, Chiba-city, Chiba, Japan

Citizenship: Japan

Post Office Address: 2-4-8, Higashi Kanda, Chiyoda-ku, Tokyo, Japan

Full name of third inventor: Takashi Kamijima

Inventor's signature Takashi Kamijima

Date 6.11.2004

Residence: 400, Misuzu, Ine-shi, Nagano

Citizenship: Japan

Post Office Address: 396-0111

2-4-8, Higashi Kanda, Chiyoda-ku, Tokyo, Japan

Full name of fourth inventor: Mika Ohta

Inventor's signature Mika Ohta

Date 6.11.2004

Residence: 6791-1 Miyoda Kamiya-gun, Nagano.

Citizenship: Japan

Post Office Address: 399-4301

2-4-8, Higashi Kanda, Chiyoda-ku, Tokyo, Japan

Send Correspondence To:  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
Customer No. 20,995

Page 3

Attorney's Docket No. RYUK-001RB

---

FOR-69

HADOCSCHAMP-1338.DOC

072503

HADOCSCHAMP-1883.DOC

000604